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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,565	07/21/2000	Miri Seiberg	JBP0510	4999

7590 02/08/2007  
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New Brunswick, NJ 08933-7003

EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

### Period for Reply

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 68-70 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 68-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/17/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 9/21/06. Examiner further acknowledges supplemental amendment filed 12/04/06.

Claims 1, 2, 68-71 are further amended in the amendment of 12/04/06 after the interview of 11/08/06. New claim 71 was presented with the amendment of 9/21/06. Claims 1-22 and 68-71 are pending.

### ***Response to Arguments***

Previous rejections that are not reiterated herein have been withdrawn.

### ***Information Disclosure Statement***

1. The information disclosure statement filed 12/04/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the non-US documents have not been considered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Claim 1 directs that after daily application of the serine protease containing composition for at least 4 weeks, hair growth, hair follicle and hair shaft size are reduced. However, the specification does not provide support for reduction of hair growth, hair follicle and hair shaft. The example 4, daily treats hair with soy-milk. Hair pigmentation determination was done at days 7-8 and day 11-12. Page 17, lines 11-17 describe applying the composition to the skin daily for four weeks and for eight weeks. This paragraph does not state determination of hair growth or hair pigmentation after the times disclosed.

***Claim Rejections - 35 USC § 103***

4. Claims 68 and 69 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Costanzo (US 6,323,219) in view of Matsuura et al. (US 6,139,899).

Costanzo discloses method and composition for “bringing about skin pigmentation and/or for causing skin depigmentation;” the methods and composition of Costanzo can be used as depigmenting compositions, darkening compositions and as compositions for preventing and/or treating immunomediated inflammatory diseases such as asthma and allergic rhinitis (abstract). The composition of Costanzo contains serine protease inhibitors that may be obtained from

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extracts of Solanaceae, Gramineae, Cucurbitaceae and Leguminosae (column 8, lines 52-67); soybean milk also contains serine protease (column 9, lines 47-53; column 28, lines 50-67).

Costanzo specifically discloses topically applying to mammalian skin pharmaceutical or cosmetic composition in an amount effective to effect changes in pigmentation (column 10, lines 13-17) and soybean milk or other formulations derived directly from legumes is applied to the mammalian skin (column 9, lines 47-52).

The instant method involves topical application to the skin a topically active composition that comprises one or more compounds derived from one or more of the botanical families. Since the instant method topically applies a composition and Costanzo topically applies to the skin a composition that reads of the instant composition, it would be inherent that the composition of the prior art affects the skin the same way as the instant composition affects the skin. The effect of the composition is inherent. Thus, although Costanzo does not specifically disclose that the composition has an effect on hair growth, since the instant claim 1 and Costanzo apply the same composition to the skin, the effect on the skin from both compositions would be the same.

Costanzo discloses the method of the instant claims, that is, topically applying a composition comprising extracts from soybeans.

Regarding claims 68 and 69, it is respectfully noted that the instant method involves application of soybean extract having trypsin inhibitory activity skin to effect inhibition of hair growth and reduction of hair follicle and hair shaft. It flows that the soybean extract of the prior art would be expected to have similar or the same effect as the soybean extract of the claims on

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the skin or hair when topically applied to the skin. Thus, in the alternate, it would be obvious for the same/similar composition to have the same/similar effect on the skin and on the hair.

However, the composition of the prior art Costanzo contains soybean milk extract. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Costanzo containing extract of soy bean milk to apply to the skin in order to effect changes in mammalian hair appearance/skin pigmentation/skin such as /pigmentation/depigmentation. One having ordinary skill in the art would have been motivated to apply the composition of Costanzo to the skin with the expectation that the composition containing the extract of would inherently have the effect of reducing/inhibiting mammalian hair growth when applied to the skin.

#### ***Response to Arguments***

5. Applicants' arguments filed 9/27/06 and 12/04/06 have been fully considered but they are not persuasive.

Applicant argues that Constanzo does not disclose the instant method because Constanzo's composition requires both melanin and SLIGRL.

#### **Response:**

Applicant's composition that is applied to the skin to effect the reduction in hair follicle size and hair growth does not exclude melanin and SLIGRL. Both the instant claims and Constanzo apply soy bean extract to the skin and it flows that the soy bean extract from the instant claims and from the prior art would have the same effect.

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6. Claims 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miljkovic (US 5,985,842).

Miljkovic describes a method of reducing hair growth by topically applying composition that comprises boron compound as a solution or emulsion in soybean oil or bile acid salt as carrier; the composition penetrates the skin stratum corneum barrier to reach the hair follicle root (abstract; column 5, lines 21-30; claim 1). While it is known in the art that soybean oil contains trypsin inhibitory activity (see Kridl, US 6,365,802 at column 10, lines 63 and 64 as a teaching reference for soybean oil containing trypsin inhibitory activity). Miljkovic does not disclose the soybean containing composition to reduce hair pigmentation. However, since the composition is applied topically to the skin effect reduction in hair growth, the composition would inherently produce other effects such as reduction in hair pigmentation, reduction in hair follicle and hair shaft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the composition of Miljkovic to the skin to reduce hair growth and expect to obtain other benefits of the soybean oil containing composition on the skin and on the hair follicle root.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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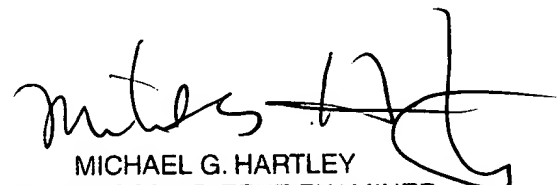
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER